REMARKS

Claims 14, 21, 22, 23, 24, 25, 26, 27, 28, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48 and 49 are pending in the instant application. Claims 14, 21, 22, 23, 24, 25, 26, 27, 28, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48 and 49 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

Rejection of Claims under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph - Lack of Enablement and Written Description

The rejection of claims 14, 21-28 and 35-49 under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, as not being supported by either a substantial utility or a well established utility has been maintained.

Claims 14, 21-28 and 35-49 also remain rejected under 35 U.S.C. 112, first paragraph for failing to meet the written description requirement.

All of these rejections are based upon the Examiner's suggestion that the specification does not teach the protein sequence or the open reading frame of SEQ ID NO:1, the Examiner's suggestion that the specification does not

provide enough information to indicate for which proteins the claimed antibodies are specific, the Examiner's suggestion that without identifying for which protein the claimed antibodies are specific in the specification, the antibodies lack utility, and the Examiner's suggestion that since the specification does not disclose identifiable structural or functional attributes of said antibodies, the specification lacks written description.

Applicants respectfully traverse these rejections.

The underlying question in each rejection raised by the Examiner is whether express written disclosure in the specification of an amino acid sequence for a protein encoded by an expressly disclosed full length nucleic acid, in this case SEQ ID NO:1, is required to meet the utility and enablement requirements as set forth in 35 U.S.C. 101 and 112, first paragraph, as well as the written description requirement set forth in 35 U.S.C. 112, first paragraph, for a claim drawn to an isolated antibody or antibody fragment that binds specifically to a protein encoded by polynucleotide sequence SEQ ID NO:1.

Applicants respectfully submit that in the instant case, with the instant facts, express written disclosure in

the specification of an amino acid sequence for a protein encoded by an expressly disclosed full length nucleic acid, in this case SEQ ID NO:1, should not be required.

While the claims have been represented for purposes of clarity, the original claim set included claims to antibodies and methods for use thereof.

MPEP 2163 states "[i]n most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for claims present in the application when originally filed, even if the specification discloses only a method of making the invention and the function of the invention. See, e.g., *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992).

Further, in *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987), the Court of Appeals for the Federal Circuit found that raising monoclonal antibodies is conventional or well known to one of ordinary skill in the art and need not be disclosed in detail. Acceptance of this decision by the United States Patent and Trademark

Office (USPTO), as it relates to the enablement requirement of 35 U.S.C. 112, first paragraph, is acknowledged by MPEP 2164.05(a), which states that the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Acceptance of this decision by the USPTO as it relates to the written description requirement of 35 U.S.C. 112, first paragraph, is clearly acknowledged by Example 13 of the Written Description Training Materials, wherein a claim drawn to an isolated antibody capable of binding to antigen X is acknowledged to meet the written description requirement of 35 U.S.C. 112, first paragraph, despite the fact that the specification does not describe actual reduction to practice of an antibody that binds antigen X by reference to a deposit or by describing an antibody in structural terms sufficient to

show possession, despite the fact that the specification does not describe the complete structure of an antibody capable of binding antigen X in detailed drawings or through a structural chemical formula, despite the fact that the specification does not describe a particular structure of the claimed antibody, and despite the fact that the specification does not describe any physical or chemical properties of the claimed antibody (e.g., molecular weight, association constant).

Accordingly, the Examiner's requirement that the specification disclose identifiable structural or functional attributes of said antibodies to meet the enablement and/or written description requirements of 35 U.S.C. 112, first paragraph, is improper.

Further, MPEP 2163 has acknowledged that "in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic

acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)." This acknowledgement by the USPTO that "it would be **unnecessary** to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence" (emphasis added) is made for determining nucleic acid sequences from an amino acid sequence where it is well known that degeneracy of the genetic code will result in multiple nucleic acid sequences. Since an explicit disclosure is not required to meet written description under these facts, Applicants believe it is improper to require explicit disclosure in the instant case, where the genetic code has been acknowledged to be widely known and degeneracy plays no factor whatsoever in determining an amino sequence that is encoded by a disclosed nucleic acid sequence.

The Examiner relies upon Fiers v. Revel, 25 USPQ2d 1601 and Amgen v. Chugai Pharmaceutical Co. Ltd. 18 USPQ 1016 to suggest that adequate written description requires more than a mere statement that it is part of the invention

and reference to a potential method of isolation; the compound itself it required. However, the facts in those cases are very different to those herein. In those cases, the claims were drawn to nucleic acid sequences for which no sequence information whatsoever was set forth in the patent application.

More relevant to the instant application are more recent decisions from the CAFC such as *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006) wherein the Federal Circuit explained that, "(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met ... even where actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure" and *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) wherein the Court state that "The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge... As each field evolves, the balance also evolves between what

is known and what is added by each inventive contribution." Also see MPEP 2163.

The genetic code, coupled with reasonable predictability associated with a proximal ATG and Kozak sequences, establishes a strong structural correlation between a nucleic acid sequence and a protein encoded thereby. A strong structural correlation between an encoded protein and antibodies raised thereto is also well-established and has been recognized by the Courts in *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986) , *cert. denied*, 480 U.S. 947 (1987), *cert. denied*, 480 U.S. 947 (1987). Further, Applicants disclose in the specification that antibodies raised against a protein encoded by the disclosed nucleic acid sequence, SEQ ID NO:1, are useful in detecting gynecologic cancers and lung cancer. Evidence confirming the disclosed utility has been submitted. Accordingly, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Express disclosure of the structure of the protein or antibodies thereto is therefore not required in

the instant application to meet the written description requirement of 35 U.S.C. 112.

Nor should express disclosure of the structure of the protein or antibodies thereto be required to meet the enablement requirements of 35 U.S.C. 112, first paragraph or the utility requirements of 35 U.S.C. 101.

MPEP 2164.01 relating to enablement and MPEP 2107 relating to utility make clear that enablement and utility are determined with respect to a person of ordinary skill in the art. Accordingly, during the prosecution of this case, Applicants have submitted Declarations by two different persons of ordinary skill in the art, specifically, Dr. Susana Salceda and Dr. Patrick Sluss addressing in detail how each understood the information disclosed in the instant specification to show possession of the claimed invention by the inventors and how each could perform experimentation routine as of the filing date of the instant application to make and use the instant claimed invention.

During prosecution of this case, Applicants have submitted evidence confirming the utility of the claimed

invention in accordance with teachings of the specification.

Applicants have also provided during prosecution of this case, evidence in the form of literature references and computer programs available prior to the filing date of the instant application demonstrative of the characteristics of the disclosed nucleic acid sequence being enabling for the claimed invention.

Finally, Applicants have identified case law and sections of the MPEP relevant to the instant fact situation supportive of express disclosure of the structure of the protein or antibodies thereto not being required in the instant fact situation.

In contrast, the Examiner has provided no specific evidence or case law relevant to the instant fact situation to support the suggestion that the specification, which expressly discloses the nucleic acid sequence of SEQ ID NO:1, does not provide enough information to indicate for which proteins the claimed antibodies are specific. The Examiner has also failed to provide any specific evidence or case law relevant to the instant fact situation to support the suggestion that without identifying for which

protein the claimed antibodies are specific in the specification, the antibodies lack utility.

Accordingly, the evidence in the prosecution history, when viewed as a whole, is indicative of the instant application meeting the written description and enablement requirements of 35 U.S.C. 112, first paragraph, and the utility requirements of 35 U.S.C. 101.

Reconsideration and withdrawal of these rejections under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, is therefore respectfully requested.

Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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